

The software was designed to collect Form No. 1 data, perform an edit-check of the entered data, print the Form No. 1, and produce a data diskette to file with the Commission. The software fulfills these design objectives.

The parties contend the software is not compatible with different types of printers. The software is compatible with all Hewlett Packard (HP) Laser Jet printers and those printers which emulate the HP standards. We were not able to anticipate all printer and printer configurations preferred by respondents. However, by using the HP standards, we were able to cover most of the respondents' printer requirements.

The parties contend the software is not designed to operate in a local area network (LAN) environment and, because it is not LAN-compatible, many companies will have to enter data twice. The software was not specifically designed to operate in a LAN environment because some respondents do not have LAN capability. Also, for those respondents that do have LANs, there are a variety of LANs in use. Ultimately, if a LAN version of the software were developed, it would require reprogramming of the software so that it would operate on any LAN. This does not mean that the software is not LAN compatible; in fact, the Commission has successfully loaded the software on the Commission's LAN and used it without problems. Also, several respondents have reported that they have been successful in operating the software on their LANs. Further, a lack of LAN compatibility does not mean that data must be entered twice by respondents. The software can be loaded on any number of personal computers where the data can be entered and stored in data files and subsequently transferred to one central personal computer.

The parties contend creation of ASCII files to import data is difficult and tedious. The creation of properly delimited ASCII files for the importing of data is difficult until a user becomes familiar with the procedure. The users' manual addresses this issue and recognizes that the necessary steps are complex. Users should consult with or seek assistance from their data processing or computer departments. Additionally, the general import feature was designed as an alternative data entry process (*i.e.*, there is no requirement that it be used).

The parties contend prior year data cannot be accessed for beginning balances, requiring re-keying of data each year. This is a correct statement, and this is one of the software changes that we are considering for future

software versions. This is not a problem for the 1994 reporting year, however, since this is the first year the software is being used and there is no prior year data to be accessed.

The parties contend state schedules identical to Form No. 1 cannot be copied with a name change, forcing complete data re-keying. This is a correct statement. However, the software is designed to not allow changes to the schedule pages. Some of the biggest problems with Form No. 1 reporting compliance have been where respondents have changed schedule formats and not reported consistent with the Form No. 1 reporting requirements. In some cases, in fact, required data were omitted or the modified formats made the reported data of limited or no use.

The parties contend there are no page up/page down keys, forcing numerous key strokes to get to the top or bottom of a page. This is a correct statement. The software was designed for data collection and if data entry is done one data field at a time, the page up/down keys are extraneous to the function.

Finally, the parties contend footnotes cannot reference multiple lines, only one field of data. This is a correct statement. The software was intentionally designed so that each individual data element could be footnoted separately and each footnote could be "linked" with the respective data element in the Commission's Form No. 1 database.

Nevertheless, while the Commission will continue to require the electronic reporting of Form No. 1 for the 1994 reporting year, the Commission recognizes that this will be the first year for such filings and additional time may be necessary to prepare such filings. Accordingly, the Commission will extend the deadline for filing Form No. 1 for the 1994 reporting year by one month, to on or before May 31, 1995.²

The Commission Orders

The requests for reconsideration of Order No. 574 are hereby denied. However, the deadline for the submission of Form No. 1 (both electronic and paper copies) for the 1994 reporting year is hereby extended from on or before April 30, 1995, to on or before May 31, 1995.

By the Commission.

Lois D. Cashell,
Secretary.

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²The one-month extension in the Form No. 1 filing deadline applies both to the electronic filing requirement and the paper copy filing requirement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority from the Commissioner of Food and Drugs to reflect recent changes to organizational structures within FDA; to update the titles of certain officials; and to reflect changes in the location and numbering of certain statutory provisions.

EFFECTIVE DATE: March 28, 1995.

FOR FURTHER INFORMATION CONTACT: Edna Morgan, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: FDA is amending certain regulations for delegations of authority in 21 CFR part 5 to reflect recent changes to organizational structures within FDA. This document removes obsolete titles and adds new titles of certain officials in various regions, districts, etc., as well as the Center for Veterinary Medicine (CVM) under the new organizational structure. The document also reflects the changes in the location and numbering of certain statutory provisions. The sections affected are as follows:

Section 5.36 *Certification following inspections* (21 CFR 5.36); § 5.37 *Issuance of reports of minor violations* (21 CFR 5.37); and § 5.63 *Detention of meat, poultry, eggs, and related products* (21 CFR 5.63).

In § 5.36, FDA is deleting the Director, St. Louis Branch from those FDA officials authorized to issue certificates of sanitation. In § 5.37(a)(4)(iii), FDA is deleting the Deputy Director, Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, from the list of officials authorized to issue certain written notices or warnings. In § 5.37(a)(6) and (b)(5), FDA is adding the Directors of the Northeast Regional Laboratory, Southeast Regional Laboratory, Winchester Engineering and Analytical Center, and National Forensic Chemistry Center to authorize these officials to issue certain written notices

or warnings. Finally, in § 5.63, FDA is deleting the Director, St. Louis Branch from those FDA officials authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs relating to detention of meat, poultry, eggs, and related products.

In § 5.37(a), FDA is changing the reference to "section 306" of the Federal Food, Drug, and Cosmetic Act to read, "section 309" to reflect renumbering accomplished by Pub. L. 102-282. In § 5.37(b), FDA is changing the reference to "section 360C(d) of the Public Health Service Act" to read "section 539(d) of the Federal Food, Drug, and Cosmetic Act" to reflect a redesignation accomplished by Pub. L. 101-629.

Further redelegation of the authority delegated is not authorized at this time. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701-1706; 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242i, 242n, 243, 262, 263, 263b, 264, 265, 300u-300u-5, 300aa-1, 300aa-25, 300aa-27, 300aa-28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660 (42 U.S.C. 300aa-1 note).

2. Section 5.36 is revised to read as follows:

§ 5.36 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under § 1240.20 of this chapter.

3. Section 5.37 is amended by revising the introductory text of paragraph (a), by

revising paragraph (a)(4)(iii), by adding new paragraphs (a)(6)(v) through (a)(6)(viii), by revising the introductory text of paragraph (b), and by revising the introductory text of paragraph (b)(5) to read as follows:

§ 5.37 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 309 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

* * * * *

(4) * * *

(iii) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

* * * * *

(6) * * *

(v) The Director, Northeast Regional Laboratory, Northeast Region.

(vi) The Director, Southeast Regional Laboratory, Southeast Region.

(vii) The Director, Winchester Engineering and Analytical Center.

(viii) The Director, National Forensic Chemistry Center.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 539(d) of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

* * * * *

(5) Regional Food and Drug Directors; District Directors; the Director, St. Louis Branch; the Director, Northeast Regional Laboratory, Northeast Region; the Director, Southeast Regional Laboratory, Southeast Region; the Director, Winchester Engineering and Analytical Center; and the Director, National Forensic Chemistry Center, when such functions relate to:

* * * * *

4. Section 5.63 is amended by revising the introductory text to read as follows:

§ 5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

* * * * *

Dated: March 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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21 CFR Part 184

[Docket No. 93P-0024]

Diacetyl Tartaric Acid Esters of Mono- and Diglycerides; Revision of Common or Usual Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulations to recognize the acronym "DATEM" as the alternate common or usual name of the ingredient diacetyl tartaric acid esters of mono- and diglycerides. This action responds to a citizen petition submitted by Grindsted Products Co. requesting approval of the alternate name.

EFFECTIVE DATE: April 27, 1995.

FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Office of Food Labeling (HFS-151), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 1, 1994 (59 FR 61560), FDA published a proposal to revise § 184.1101(a) and (e) (21 CFR 184.1101(a) and (e)) on diacetyl tartaric acid esters of mono- and diglycerides to provide for the use of the acronym "DATEM" in food labeling as the alternate common or usual name of this ingredient. The proposal was issued in response to a citizen petition submitted by Grindsted Products Co. No comments were received by the agency in response to the proposal.

II. Conclusion

The agency received no comments on the proposed rule. Thus, the agency concludes that, for the reasons set forth in its proposal, it is appropriate to revise § 184.1101 (e) governing generally recognized as safe (GRAS) food substances to provide for the use of the acronym "DATEM" as the alternate common or usual name of the ingredient diacetyl tartaric acid esters of mono- and diglycerides on food labeling. The agency concludes that there has been sufficient exposure to the term "DATEM" to allow the American consumer to recognize and understand the meaning of this term. The term "DATEM" is acceptable and favorable to both industry and the consumer and, therefore, should be allowed to be used interchangeably with the term "diacetyl tartaric acid esters of mono- and diglycerides."